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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,285	07/12/2000	Daniel E. H. Afar	129.9US11	3235

7590 02/26/2002

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EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/615,285	Applicant(s) AFAR ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 39-47* is/are pending in the application.

4a) Of the above claim(s) *14,20-28 and 39-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,13 and 15-19* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

The Election filed January 15, 2002 (Paper No. 8) in response to the Office Action of October 2, 2001 is acknowledged and has been entered. Claims 29-38 were cancelled. Claims 1, 6-7, 20, 23 and 28 were amended. Claims 39-47 were added. Currently, claims 1-28, and 39-47 are pending in the application. Also attached is an interview summary conducted February 11, 2002 in which it was agreed that applicants could change their species election. The original species election (Paper No. 8, received 1-15-02, page 6) was to mRNA expression, immunoassay, blood and serum and prostate cancer. As a result of the interview, the NEW species are as follow: protein expression, immunoassay, biopsied tissue, and prostate cancer. Claims 14, 20-28, and 39-47 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1-13 and 15-19 are currently under consideration.

Applicant's election with traverse of Group I, claims 1-19 in Paper No 7 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I and II do not represent patentably distinct inventions and at the least the alleged differences in "objectives" and "criteria of success" do not appear to be proper bases for restriction since restriction requires distinctness and independence between the claimed invention and a serous burden of search. This is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in Paper No. 7. Furthermore, the invention of Group II materially differs from the invention of Group I by including an additional step for the presence

of a factor which is not assayed in the invention of Group I. It is noted that there was no traversal of the elected species.

As to the question of burden of search, the literature search relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Priority

This application claims priority to three provisional applications- 60/087,598 filed 06/01/98; 60/091,474 filed 06/29/98, and 60/129,521 filed 04/14/99. Provisional applications 60/087,598 and 60/091,474 do not have an adequate written description of for the gene encoding the sequence of 20P1F12/TMPRSS2 (SEQ ID NO:2). Thus, the examiner has established the priority date according to provisional application No: 60/129,521 filed April 14, 1999.

If applicant disagrees with any rejection set forth in this office action based on examiner's establishment of a priority date of 04/14/99 for the instantly claimed application serial number 09/615285, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Specification

The specification on page 1 should be amended to reflect the priority status of the present application, for example- applicant should indicate that all three provisional applications are now abandoned.

The specification is further objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 17, line 6, and page 31, line 28). Applicant is required to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

The specification is further objected to on pages 29-30 for improper disclosure of amino acid sequences without a respective sequence identifier, i.e. a SEQ ID NOs:. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. (see MPEP 2422). In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). (See attached notice to comply.)

The specification is further objected to on pages 39-40, for missing ATCC information. Applicant is required to supply the ATCC designations.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, and 4-7 are rejected as vague and indefinite for reciting "status of 20P1F12/TMPRSS2" as the sole means of for determining evidence of dysregulated cellular growth in a biological sample. The "status" of the gene is open to interpretation and the specification does not provide a *limiting* definition to complete the methods as claimed. For example, the specification teaches (page 60, line 27) that the term "status" is used according to its art accepted meaning and refers to the "condition or state of a gene and its products". This definition is non-limiting because it does not distinctly define what aspect of a genetic status is to be examined. And, although the specification teaches what may be considered as evaluating a status (i.e. examining the sequence of 20P1F12/TMPRSS2 or the levels of 20P1F12/TMPRSS2) such examples do not specifically limit what *specific* status is to be examined in the claimed method steps. Hence the metes and bounds of the claims cannot be determined.

Claim 3 is rejected as vague for reciting "20P1F12/TMPRSS2 immunoreactive complex" as it is not clear what is included or excluded as an immunoreactive complex- an antibody?, an enzyme?, a species of 20P1F12/TMPRSS2 etc. Hence, the methods steps are not distinct and are open to interpretation. Without a distinct definition of what complex is being considered, the metes and bounds of the claims cannot be determined.

Claims 8-9 and 17-19 are rejected as vague for reciting "binding partner" as the specification does not define what is included or excluded as a binding partner. A binding partner can be anything in the world which complexes to the polypeptide of interest, i.e. an antibody, an

enzyme, a peptide, a substrate, etc. Hence, the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 7-10, 12-13, and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong *et al.* (US Patent No. 6,166,194, June 29, 1998).

The claims are broadly drawn to a method of examining a biological sample for evidence of dysregulated cellular growth comprising comparing the status of 20P1F12/TMPRSS2 in the biological sample to the status of 20P1F12/TMPRSS2 in a corresponding normal sample, wherein alterations in the status of 20P1F12/TMPRSS2 in the biological sample are associated with dysregulated cellular growth (Claim 1); wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by examining levels of 20P1F12/TMPRSS2 protein expression

(Claim 2); wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by observing the presence or absence of a 20P1F12/TMPRSS2 immunoreactive complex (Claim 3); wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by immunoassay (Claim 4); wherein the biological sample is a biopsied tissue (Claim 5); wherein the dysregulated cell growth is indicative of a colon cancer (Claim 7); wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by an immunoassay which measures the concentration of a free 20P1F12/TMPRSS2 polypeptide, the concentration of 20P1F12/TMPRSS2 polypeptide complexed to a binding partner or the ratio comparing the concentration of the free 20P1F12/TMPRSS2 polypeptide to the concentration of the 20P1F12/TMPRSS2 polypeptide complexed to a binding partner (Claim 8); wherein the 20P1F12/TMPRSS2 evaluated in the biological sample is secreted from cells exhibiting dysregulated growth (Claim 9).

The claims are further drawn to a method of identifying evidence of a neoplasm in a biological sample comprising examining a level of 20P1F12/TMPRSS2 gene expression in a test biological sample; comparing the level of 20P1F12/TMPRSS2 gene expression in the test biological sample to a level of 20P1F12/TMPRSS2 gene expression found in a comparable normal biological sample, wherein differences in the level of 20P1F12/TMPRSS2 gene products in the test biological sample relative to the normal biological sample are associated with the neoplasm (Claim 10); wherein the neoplasm is a colon cancer (Claim 12); wherein the test biological sample is biopsied tissue (Claim 13); wherein the level of 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by examining the level of 20P1F12/TMPRSS2 protein expression (Claim 15); wherein the level of 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by immunoassay (Claim 16); wherein

the level of 20P1F12/TMPRSS2 gene expression in a test biological sample is evaluated by an immunoassay which measures the concentration of free 20P1F12/TMPRSS2 polypeptide or the concentration of 20P1F12/TMPRSS2 polypeptide complexed to a binding partner (Claim 17); wherein the 20P1F12/TMPRSS2 evaluated in the test biological sample is secreted from cells exhibiting dysregulated growth (Claim 18).

Wong *et al.* teach the relation of the TMPRSS2 gene to human cancers and its use in the diagnosis and prognosis of cancer. As evidenced by the attached sequence comparison, the TMPRSS2 gene taught by Wong *et al.* is 100% identical to applicant's claimed 20P1F12/TMPRSS2 polypeptide which may be isolated by immunological means in isolated and/or purified form, free or substantially free of material with which it is naturally associated using protein purification techniques well known in the art (**column 16, lines 23-26, column 20, lines 16-25**).

Wong *et al.* further teach methods of examining a biological sample for evidence of dysregulated cellular growth comprising comparing the status of 20P1F12/TMPRSS2 in the biological sample to the status of 20P1F12/TMPRSS2 in a corresponding normal sample (and or identifying evidence of a neoplasm in a biological sample comprising examining a level of 20P1F12/TMPRSS2 gene expression in a test biological sample) wherein alterations in the status of 20P1F12/TMPRSS2 in the biological sample or levels of gene expression are associated with dysregulated cellular growth; wherein the status and or levels of 20P1F12/TMPRSS2 in the biological sample is evaluated by examining levels of 20P1F12/TMPRSS2 protein expression; wherein the status or levels of 20P1F12/TMPRSS2 in the biological sample is evaluated by observing the presence or absence of a 20P1F12/TMPRSS2 immunoreactive complex (**columns**

9, lines 27-67; column 28, lines 52-63) wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by immunoassay; wherein the biological sample is a biopsied tissue (**column 12, lines 55-63**); wherein the dysregulated cell growth is indicative of a colon cancer (**column 13, lines 25-28**). wherein the 20P1F12/TMPRSS2 evaluated in the biological sample is secreted from cells exhibiting dysregulated growth (**column 9 lines 65-66; column 10, lines 1-17**).

Claim Objections

Claim 2 is objected to as being drawn, in part, to a non-elected invention. The species of mRNA expression was not considered because the elected species reads on protein expression. Hence, applicant should amend the claim so that it no longer reads on the non-elected species.

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
February 20, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

GenCore version 4.5

OM protein - protein search, using sw model

Run on: September 26, 2001, 09:21:05 ; Search time 20.35 Seconds
(without alignments)
497.811 Million cell updates/sec

Title: US-09-615-285-2
Perfect score: 2717
Sequence: 1 MALNSGSPPAIGPYYENHGY.....VYGNVMVFTDWIYRQMRADG 492

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Post-processing: Minimum Match 0%
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Listing first 45 summaries

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
1	2717	100.0	492	4	US-09-342-749-2	Sequence 2, Appli
2	1540	56.7	283	3	US-08-807-151-1	Sequence 1, Appli
3	676.5	24.9	435	4	US-09-008-271A-6	Sequence 6, Appli
4	660	24.3	798	1	US-08-200-900A-2	Sequence 2, Appli
5	660	24.3	798	5	PCT-US94-00616-2	Sequence 2, Appli
6	558.5	20.6	855	2	US-09-027-337-2	Sequence 2, Appli
7	556	20.5	638	2	US-08-681-151-3	Sequence 3, Appli
8	553.5	20.4	248	4	US-08-944-483-63	Sequence 63, Appl
9	539.5	19.9	416	2	US-09-000-846-2	Sequence 2, Appli
10	534	19.7	356	2	US-08-681-151-1	Sequence 1, Appli
11	528.5	19.5	256	2	US-09-027-337-3	Sequence 3, Appli
12	527.5	19.4	418	1	US-08-508-448C-25	Sequence 25, Appl
13	524	19.3	238	4	US-08-944-483-64	Sequence 64, Appl
14	523.5	19.3	255	4	US-08-944-483-67	Sequence 67, Appl
15	521.5	19.2	235	3	US-08-807-151-3	Sequence 3, Appli
16	518.5	19.1	812	1	US-08-248-629A-1	Sequence 1, Appli
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19	518.5	19.1	812	1	US-08-326-785-1	Sequence 1, Appli
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28	495.5	18.2	250	4	US-08-944-483-68	Sequence 68, Appl
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30	452	16.6	546	6	5200340-6	Patent No. 5200340
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32	449	16.5	655	1	US-08-148-910-12	Sequence 12, Appl
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34	447	16.5	276	2	US-09-016-366A-15	Sequence 15, Appl
35	447	16.5	276	2	US-08-978-404B-21	Sequence 21, Appl
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44	445.5	16.4	810	1	US-07-854-603-2	Sequence 2, Appli
45	445.5	16.4	810	1	US-08-147-000B-29	Sequence 29, Appl

ALIGNMENTS

RESULT 1
US-09-342-749-2
; Sequence 2, Application US/09342749
; Patent No. 6166194
; GENERAL INFORMATION:
; APPLICANT: Wong, Alexander K.C.
; APPLICANT: Tavtigian, Sean V.
; APPLICANT: Teng, DAvid H.-F.
; APPLICANT: Myriad Genetics, Inc.
; TITLE OF INVENTION: TMPRSS2 is a Tumor Suppressor
; FILE REFERENCE: 2318-202
; CURRENT APPLICATION NUMBER: US/09/342,749
; CURRENT FILING DATE: 1999-06-29
; EARLIER APPLICATION NUMBER: US 60/091,044
; EARLIER FILING DATE: 1998-06-29
; NUMBER OF SEQ ID NOS: 33
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 2
; LENGTH: 492
; TYPE: PRT
; ORGANISM: Homo sapiens
US-09-342-749-2

Query Match 100.0%; Score 2717; DB 4; Length 492;
Best Local Similarity 100.0%; Pred. No. 2.1e-241;
Matches 492; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Db     481 TDWIYRQMRADG 492
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RESULT   2
US-08-807-151-1
; Sequence 1, Application US/08807151
; Patent No. 6043033
;  GENERAL INFORMATION:
;    APPLICANT:  Bandman, Olga
;    APPLICANT:  Lal, Preeti
;    TITLE OF INVENTION:  NOVEL HUMAN PROSTATE-ASSOCIATED
;    TITLE OF INVENTION:  PROTEASE
;    NUMBER OF SEQUENCES:  5
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Incyte Pharmaceuticals, Inc.
;      STREET:  3174 Porter Drive
;      CITY:  Palo Alto
;      STATE:  CA
;      COUNTRY:  US
;      ZIP:  94304
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Diskette
;      COMPUTER:  IBM Compatible
;      OPERATING SYSTEM:  DOS
;      SOFTWARE:  FastSEQ Version 2.0
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/807,151
;      FILING DATE:  Filed Herewith
;      CLASSIFICATION:  424
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:
;      FILING DATE:
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Billings, Lucy J.
;      REGISTRATION NUMBER:  36,749
;      REFERENCE/DOCKET NUMBER:  PF-0227 US
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  415-855-0555
;      TELEFAX:  415-845-4166
;  INFORMATION FOR SEQ ID NO:  1:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  283 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:  single
;      TOPOLOGY:  linear
;    IMMEDIATE SOURCE:
;      LIBRARY:  SCORN0T01
;      CLONE:  556016
US-08-807-151-1


  Query Match             56.7%;  Score 1540;  DB 3;  Length 283;
  Best Local Similarity   99.6%;  Pred. No. 1.3e-133;
  Matches  282;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;

Qy     210 MKLNTSAGNVDIYKKLYHSDACSSKAVVSLRCIACGVNLNSSRQSRIVGGESALPGAWPW 269
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
           1 MKLNTSAGNVDIYKKLYHSDACSSKAVVSLRCIACGVNLNSSRQSRIVGGESALPGAWPW 60

           QVSLHVQNVHVCGGSIITPEWIVTAAHCVEKPLNNPWHWTAFAGILRQSFMFYGAGYQVE 329
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db      61 QVSLHVQNVHVCGGSIITPEWIVTAAHCVEKPLNNPWHWTAFAGILRQSFMFYGAGYQVE 120

Qy     330 KVISHPNYDSKTKNNDIALMKLQKPLTFNDLVKPVCLPNPGMMLQPEQLCWISGWGATEE 389
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 KVISHPNYDSKTKNNDIALMKLQKPLTFNDLVKPVCLPNPGMMLQPEQLCWISGWGATEE 180

Qy     390 KGKTSEVLNAAKVLLIETQRCNSRYVYDNLITPAMICAGFLQGNVDSCQGDSGGPLVTSK 449
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||| |||||
Db     181 KGKTSEVLNAAKVLLIETQRCNSRYVYDNLITPAMICAGFLQGNVDSCQGDSGGXLVTSK 240

Qy     450 NNIWWLIGDTSWGSGCAKAYRPGVYGNVMVFTDWIYRQMRADG 492
           |||||||||||||||||||||||||||||||||||||||||||||
Db     241 NNIWWLIGDTSWGSGCAKAYRPGVYGNVMVFTDWIYRQMRADG 283
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```
RESULT   3
US-09-008-271A-6
; Sequence 6, Application US/09008271A
; Patent No. 6203979
;   GENERAL INFORMATION:
;        APPLICANT: Bandman, Olga
;                   Hillman, Jennifer L.
;                   Yue, Henry
;                   Guegler, Karl J.
;                   Corley, Neil C.
;                   Tang, Tom Y.
;                   Shah, Purvi
;        TITLE OF INVENTION: HUMAN PROTEASE MOLECULES
;        NUMBER OF SEQUENCES: 24
;        CORRESPONDENCE ADDRESS:
;             ADDRESSEE: Incyte Pharmaceuticals, Inc.
;             STREET: 3174 Porter Dr.
;             CITY: Palo Alto
;             STATE: CA
;             COUNTRY: USA
;             ZIP: 94304
;        COMPUTER READABLE FORM:
;             MEDIUM TYPE: Diskette
;             COMPUTER: IBM Compatible
;             OPERATING SYSTEM: DOS
;             SOFTWARE: FastSEQ for Windows Version 2.0
;        CURRENT APPLICATION DATA:
;             APPLICATION NUMBER: US/09/008,271A
;             FILING DATE: 16-Jan-1998
;        PRIOR APPLICATION DATA:
;             APPLICATION NUMBER: <Unknown>
;             FILING DATE: <Unknown>
;        ATTORNEY/AGENT INFORMATION:
;             NAME: Mohan-Peterson, Sheela
;             REGISTRATION NUMBER: 41,201
;             REFERENCE/DOCKET NUMBER: PF-0458 US
;        TELECOMMUNICATION INFORMATION:
;             TELEPHONE: 650-855-0555
;             TELEFAX: 650-845-4166
;   INFORMATION FOR SEQ ID NO: 6:
;        SEQUENCE CHARACTERISTICS:
;             LENGTH: 435 amino acids
;             TYPE: amino acid
;             STRANDEDNESS: single
;             TOPOLOGY: linear
;        IMMEDIATE SOURCE:
;             LIBRARY: COLNNOT13
;             CLONE: 1337018
;        SEQUENCE DESCRIPTION: SEQ ID NO: 6 :
US-09-008-271A-6


  Query Match             24.9%;  Score 676.5;  DB 4;  Length 435;
  Best Local Similarity   39.1%;  Pred. No. 5e-54;
  Matches  150;  Conservative   57;  Mismatches  128;  Indels   49;  Gaps   13;

Qy     133 CDGVSHCPGGEDENRCVRLY--GP---------NFILQVYSSQRKSWHPVCQDDWNENYG 181
           |||   || ||||  ||: :  ||           |||  |   :|   | |:: |
```

Application No. 09/615285

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other:

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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